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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,440	04/13/2001	Omar S. Khalil	6800.US.O1	2947

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EXAMINER	
WINAKUR, ERIC FRANK	
ART UNIT	**PAPER NUMBER**
3735	

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,440	KHALIL ET AL.	
	Examiner	Art Unit	
	Eric F. Winakur	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 19 September 2005 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7 and 9 - 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of U.S. Patent 5,028,787 to Rosenthal et al. Mills teaches a device for non-invasively determining oxygen saturation, partial pressure of oxygen, partial pressure of carbon dioxide, concentration of bicarbonate ion and total carbon dioxide, acid-base balance, base excess, hemoglobin level, hematocrit, oxyhemoglobin level, deoxyhemoglobin level, and oxygen content. (Abstract of Mills). Mills teaches measurement from finger, tubing, or other space of interest (column 9, lines 1 - 14 of Mills) and that two probes at different locations at two different temperatures are used to calculate oxygen saturation (column 12, lines 6-42 of Mills).

Mills teaches a mathematical relationship (column 9, line 56 to column 11, line 56 of Mills). In regard to claims 1 and 7, the device can be used to detect cancers (column 14, lines 20-25 of Mills). In regard to claims 2 and 10, 660nm and 940 nm can be used. (Fig. 11 of Mills). In regard to claims 3 and 11, reflectance can be employed (column 8, lines 1-3 of Mills). In regard to claims 4 and 12, simultaneous measurements can be taken (column 12, lines 6-22 of Mills). In regard to claims 6 and 14, temperatures ranging from 33-40 °C can be used (column 12, lines 6-42 of Mills). In regard to claims 9 and 16, the device can be used to determine glucose (column 13, lines 28-42 of Mills). Mills teaches all of the features of the claimed invention except that the measurement is performed on a first and second area of a part of the arm. Rosenthal et al. teach that portions of an arm (crease of the elbow, wrist) and a finger tip are alternate locations for performing optical measurements and that transmission or reflection measurements can be performed at the locations, as appropriate (column 4, lines 1 - 41 of Rosenthal). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mills to perform the measurements on portions of a subject's arm since Rosenthal teaches that finger tip and arm are alternate equivalent locations for such measurements. Further, one of ordinary skill would take the teaching of Mills regarding the requirements for the temperature regulation into account when determining appropriate locations on the arm from which to perform the measurements. As such, one would perform measurements from adjacent, but not substantially overlapping portions of the subject's arm to allow precise temperature regulation of the measured areas; all portions of a subject's arm are considered to be morphologically similar.

With regard to claims regard to claims 5 and 13, Mills does not teach an embodiment in which the two probe locations are taking measurements at different temperatures in a sequential fashion. Mills teaches two probe locations in which measurements are taken at different temperatures simultaneously (column 12, lines 6-13 of Mills). Mills also teaches a single probe location in which measurements are taken at different temperatures in a sequential fashion (column 11, lines 59-67 of Mills). Mills is implying that his method does not require that both measurements at different temperatures are taken simultaneously since one method allows for sequential measurements. This implication would lead to one with ordinary skill in the art to believe that sequential measurements are a valid option if desired due to design considerations. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination with multiple measurement locations to include sequential measurement taking since Mills implies that such a method is valid.

In regard to claim 15, Mills does not explicitly teach providing a population comprising a sufficient number of subjects to establish a category selector or to establish a statistically meaningful relationship. Mills teaches the use of normal volunteers during calibrating mathematical relations (column 9, lines 44-53 of Mills). It is known in the art that calibration using human subjects is performed when determining a computation model for an optical diagnostic device. It is also well known in the art that the required accuracy of the model and the availability of subjects are factors to determining when determining calibration procedures. This information provides a clear

suggestion that the number of subjects can be modified and that the determination of the most appropriate number of subjects by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Mills and Rosenthal as applied to claim 1 above, and further in view of Patent 5,800,347 to Skates et al. Mills does not explicitly teach of providing a population comprising a sufficient number of subjects to establish a category selector in which the number of subjects comprises a sub-population of humans in a disease state and a sub-population of humans not in a disease state. Mills teaches the use of normal volunteers during calibrating mathematical relations (column 9, lines 44-53 of Mills). Mills implies that such calibration using human subjects is used when determining a computation model for an optical diagnostic device. It is also well known in the art that the required accuracy of the model and the availability of subjects are factors to determining when determining calibration procedures. One method of establishing mathematical relations from calibration is using a statistical analysis of measurements on normal and diseased populations to establish multivariate algorithms. (Abstract of Skates et al.). Such multivariate algorithms are used to establish measurement thresholds to aid in diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold (column 4, lines 16-53 of Skates et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the calibration method as disclosed by Skates et al. in the method and apparatus of the combination since multivariate

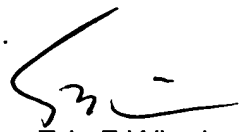
algorithms are used to establish measurement thresholds to aid in diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam can be reached on 571/272-4737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3735

8 December 2005